REMARKS/ARGUMENTS

The Office Action dated March 21, 2003 has been carefully reviewed. Claims 1-24 are presented for examination. No claims stand allowed.

Claims 1-24 are rejected under 35 U.S.C. §112, second paragraph, as being unpatentable for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is deemed to be indefinite because although it reads on a method of preventing the development of Type II diabetes, it also states that the subject mammal is "afflicted with such condition". By the present amendment claim 1 has been amended by deleting the words "in mammals afflicted with such condition with" and by adding the words "comprising administering to a mammal" before the words "a therapeutically effective amount".

Claims 5 and 15 are deemed to be indefinite because although they read on a method of preventing Syndrome X and skin lesions associated with Type II diabetes mellitus or Syndrome X respectively they also state that the subject mammal is afflicted with such conditions. By the present amendment claims 5 and 15 have been amended by deleting the words "in mammals afflicted with such condition with" and by adding the words "comprising administering to a mammal" before the words "a therapeutically effective amount" in each instance.

Claims 1, 6, 10, 15 and 20 are deemed to be indefinite because they fail to recite any of the steps of the method. As indicated above claims 1 and 15 have been amended to recite the steps of the method. Claim 6 is dependent upon claim 5 which also has been amended to recite the steps of the method. Claim 10 has been amended by adding the words "comprising administering to a mammal" before the words "afflicted with".

Claim 5 is deemed to be indefinite because it is not clear whether the parenthetical expression "(Insulin Resistance Syndrome, Metabolic Syndrome, or Metabolic Syndrome X)" is intended to limit the claim. The language employed in the claim was not intended to limit the claim in any way. By the present amendment the language objected to by the Examiner has been deleted.

Reconsideration of the rejection of claims 1-24 as being unpatentable under 35 U.S.C. §112, second paragraph, is courteously requested.

Claims 1, 2, 10, 11, 15, 16, 20 and 21 are rejected under 35 U.S.C. §102(a) and/or (b) as being anticipated by Edwards *et al.* (U). The Examiner has concluded that Edwards teaches the administration of topiramate for the treatment of diabetic neuropathy in patients suffering from diabetes. Applicant wishes to point out that the subject matter of Edwards *et al.* is "The Evaluation of Topiramate in the Management of Painful Diabetic Neuropathy". Patients with diabetes frequently suffer painful neuropathy. Edwards *et al.* stands for the

proposition that topiramate is effective in treating pain associated with diabetes. According to the last sentence in the abstract "The majority of patients received substantial reduction of pain and improvement of quality of life for treatment of painful diabetic neuropathy with topiramate". There is nothing in Edwards *et al.* to indicate that topiramate is useful for preventing the onset of Type II diabetes. There is nothing in Edwards *et al.* to indicate that topiramate is useful in treating Type II diabetes. There is no basis for the conclusion by the Examiner that at least some of the 26 patients treated by Edwards *et al.* had Type II diabetes since the object of the researchers was to treat the painful neuropathy associated with diabetes.

Nowhere in the abstract is it stated that "the patients of Edwards are mammals suffering from impaired oral glucose tolerance" as indicated by the Examiner. Therefore, contrary to the conclusion reached by the Examiner, there is no anticipation of the subject matter of claim 10. The fact that the abstract is silent as to the existence of skin lesions in the patients participating in the study does not mean that the abstract discloses that topiramate is useful in preventing the development of skin lesions. The abstract, therefore, does not anticipate the subject matter of claim 15 as indicated by the Examiner. There is no basis in the abstract for the Examiner's conclusion that the patients treated by Edwards *et al.* are mammals suffering from defective insulin sensitivity. The limitations in claim 20, therefore, are not met by the disclosure in Edwards *et al.* Edwards *et al.* merely stands for the proposition that topiramate is useful in treating painful neuropathy in patients with diabetes and nothing more. It is submitted that the conclusions reached by the Examiner based on the disclosure in Edwards *et al.* as to the prevention of diabetes and the prevention of the development of skin lesions with topiramate are purely conjectural and are not supported by the disclosure in the reference. In order to constitute anticipation all material elements of a claim must be formed in one prior art source. It is submitted that all of the material elements of applicant's claims are not found in Edwards *et al.*

Reconsideration of the rejection of claims 1, 2, 10, 11, 15, 16, 20 and 21 under 35 U.S.C. §102(a) and/or (b) as being anticipated by Edwards *et al.* (U) is courteously requested.

Claims 1-24 are rejected under 35 U.S.C. §102(a) and/or (b) as being anticipated by Osborne *et al.* (BA);

Claims 1-24 are rejected under 35 U.S.C. §102(a) and/or (b) as being anticipated by Demarest *et al.* (BC);

Claims 1-9 and 15-19 are rejected under 35 U.S.C. §102(a) and/or (b) as being anticipated by Crooke *et al.* (BE);

Claims 1-24 are rejected under 35 U.S.C. §102(a) and/or (b) as being anticipated by Demarest *et al.* (BF);

Claims 1-9 and 15-19 are rejected under 35 U.S.C. §102(a) and/or (b) as being anticipated by Osborne *et al.* (BG); and

Claims 1-9 and 15-19 are rejected under 35 U.S.C. §102(a) and/or (b) as being anticipated by Shank (CA).

All of the above references cited by the Examiner under 35 U.S.C. §102(a) and/or (b), with the exception of Shank, are abstracts which were published in "diabetes" which is a journal of the American Diabetes Association. They appeared in the ABSTRACT BOOK of the 61st Scientific Sessions which were held between Friday June 22 and Tuesday June 26, 2001. A copy of the cover page of the journal and of each of the original abstracts is enclosed. The present application is based on provisional application Ser. No. 60/217,141 which was filed on July 7, 2000 and provisional application Ser. No. 60/270,022, filed February 20, 2001. Since applicant's effective filing date precedes the publication date of each of the abstracts in question, it is submitted that none of the cited references, with the exception of Shank, is a valid reference against applicant's application. (Applicant wishes to point out that the cited Osborne *et al.* abstracts are one and the same abstract and that the Demarest *et al.* abstracts are also one and the same abstract.)

The Examiner has pointed out on page 2 of the office action that "no dates have been provided with references BA-BG submitted with the Information Disclosure Statement of 08-29-01. Applicant is submitting herewith a new Information Disclosure Statement (IDS) which bears the date of the publication of the journal of the American Diabetes Association in which the Osborne *et al.*, Demarest *et al.* and the Crooke *et al.* abstracts appear.

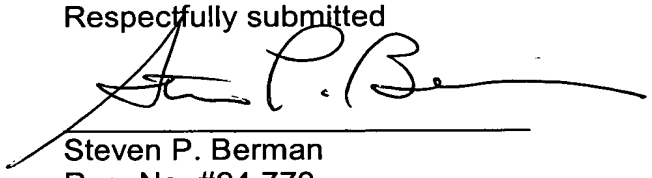
The Shank reference is U.S. patent No. 6,071,537. In rejecting applicant's claims the Examiner has pointed out that Shank teaches the administration of compounds within the scope of the pending claims, including topiramate, at a dosage of about 50-400 mg or about 25 to 200 mg to mammals suffering from obesity and concludes that the pending claims are anticipated as to prevention. The subject matter of the '537 patent is a method of treating obesity with compounds similar in scope to those of the pending claims. There is no disclosure in the '537 patent remotely relating to Type II diabetes or Syndrome X. There is nothing in the '537 patent that would even suggest that the compounds in question could be used to prevent the onset of Type II diabetes or Syndrome X.
The mere fact that similar dosages of the compounds employed in applicant's invention may be employed in the treatment of obesity does not in any way mean that the disclosure in the '537 patent is an anticipation of applicant's invention which relates to the prevention of the onset of Type II diabetes and Syndrome X. In order to anticipate an invention all material elements of a claim must be present in one prior art reference. There is no direct correlation between obesity and Type II diabetes or obesity and Syndrome X. The use of similar doses of the compounds to treat obesity does not in any way anticipate the use of similar

doses of the compounds to prevent the onset of Type II diabetes or Syndrome X. The Shank patent, therefore, is not an anticipation of applicant's invention.

Reconsideration of the rejection of claims 1-24 under 35 U.S.C. §102(a) and/or (b) is courteously requested.

In view of the above discussion and the amendments herein being made to the claims, it is believed that all of the outstanding objections and rejections have been removed. A favorable disposition of the application is courteously requested.

Respectfully submitted



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